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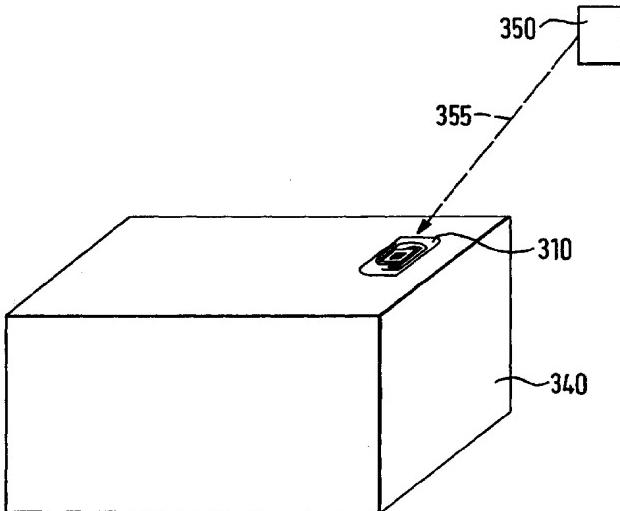
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(54) Title: MONITORING METHOD



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(57) **Abstract:** There is provided a method for tracking environmental exposure of an object comprising selecting the object; associating a radiofrequency identifier with the object, the radiofrequency identifier comprising an antenna for transmitting or receiving radiofrequency energy; and an integrated circuit chip connecting with said antenna, said chip having a memory; exposing the object to an environmental condition; measuring environmental condition as an environmental parameter with a sensor physically separate from the radiofrequency identifier; and writing the environmental parameter to the memory of the chip by transmitting radiofrequency energy thereto.



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**METHOD FOR MONITORING OBJECTS WITH TRANSPONDERS**

- 5      The present invention relates to a method of monitoring exposure of an object to environmental conditions. In particular, it relates to a method of tracking environmental exposure of medicaments and medical devices to a range of environmental conditions using radio frequency identification tags.
- 10     Exposure to environmental conditions, such as temperature, moisture and pressure, can have a marked effect upon the storage or shelf life of many products. Many chemicals and biological products, for example those used in medicaments, are sensitive to changes in temperature and/or moisture, with relatively small variations in either leading to instability and breakdown due to
- 15     chemical hydrolysis and/or microbial decay. Product stability may also be influenced by light and UV levels, necessitating the incorporation of various UV stabilisers in many chemical and biological formulations.
- A wide range of other products are also sensitive to environmental change.
- 20     Foodstuffs, such as fresh foods and drinks, are extremely susceptible to temperature fluctuations, both high and low temperatures causing deterioration in the quality of the food or drink due to chemical and/or microbiological degradation.
- 25     The manufacture and distribution of many products, particularly medicaments, requires careful monitoring of environmental exposure to ensure compliance with product specifications. Manufacturers are known to incorporate sensors of various types into their products in order that they can monitor environmental exposure and thereby the quality of their product. For example, temperature
- 30     sensors are used in the food industry to indicate the temperature of food products and even record their previous exposure to a range of temperatures.

Similar devices are employed to indicate whether frozen foodstuffs have been allowed to thaw and refreeze.

These methods, however, are expensive as they require individual sensors to be attached to each product.

5

The Applicants have now devised an improved method of monitoring environmental exposure of a product, particularly from the point of manufacture to sales. Furthermore, the method can be used to check environmental compliance of the product throughout the manufacture-distribution-storage

10 process. The method involves associating a passive radiofrequency identification (RFID) tag or transponder with an object, or a container for the object, and writing environmental data to the tag from a separate sensor exposed to the same environmental conditions. The environmental data are read, on energising by a reader/writer, either continuously or at defined points

15 throughout the manufacture-distribution-storage process and checked for compliance against defined criteria. Non-compliance results in rejection of the object and/or recall of the object by the manufacturer. Alternatively, non-compliance may result in a reduction of the effective shelf-life of the object, as in the case of medicaments and perishable goods.

20

The RFID tag can be configured to have a memory structure which allows for large amounts of discrete information to be stored thereon. Transfer of information to or from the memory is readily achievable by the use of a reader/writer which is typically remote from the object, thereby minimising the need for direct product handling. In further aspects, the reader/writer can be arranged to simultaneously read, or write to, the memory of multiple RFID tags on multiple objects.

25 A principal advantage of the present invention is the capability of the memory of the RFID tag to store many environmental data items which are written to the memory at various defined points in the manufacturing-distribution-storage

- process. The memory thereby provides a detailed and readily accessible 'environmental exposure' history. The environmental information could, for example, also include date and time stamps. The memory might also be configured to include a unique serial number stored in encrypted form or in a password protectable part of the memory which uniquely identifies the product.
- 5 The information could also include basic product information such as the nature of the product and usage information, customer information and distribution information such as the intended product destination.
- 10 The use of RFID tags to monitor environmental exposure is known in the art. Thus GB 2308947 discloses RFID tags having sensors incorporated within the transponder which can transmit environmental data to a remote reader on energising therefrom. Similar devices relating to RFID tags possessing built-in sensors are described for biomedical GB 2297225 and agricultural GB 2249001,
- 15 GB 2076259 applications.

The principal advantages of the Applicant's invention over those disclosed in the literature are those of simplicity and cost. By eliminating the need to build individual sensors into each tag the Applicant's have devised a simplified method

20 of monitoring environmental exposure at significantly reduced cost to the user.

According to one aspect of the present invention there is provided a method for tracking environmental exposure of an object comprising selecting an object; associating a radiofrequency identifier with the object, the

25 radiofrequency identifier comprising an antenna for transmitting or receiving radiofrequency energy; and an integrated circuit chip connecting with the antenna, the chip having a memory; exposing the object to an environmental condition; measuring the environmental condition as an environmental parameter with a sensor physically separate from the radiofrequency identifier;

30 and writing the environmental parameter to the memory of the chip by transmitting radiofrequency energy thereto.

The object may be exposed to environmental conditions throughout its lifetime. Whilst environmental conditions are likely to be stringently controlled during the manufacturing process this is not always necessarily the case in all industries and in all manufacturing localities. Variation in environmental conditions are  
5 most likely during product transport and storage; for example, transport at reduced temperatures and pressures during air freight, or on delivery to storage depots in the tropics.

The radiofrequency identifier can be any known radiofrequency identifier. Such  
10 identifiers are sometimes known as radiofrequency transponders or radiofrequency identification tags. Suitable radiofrequency identifiers include those sold by Phillips Semiconductors of the Netherlands under the trade marks Hitag, and Icode those sold by Amtech Systems Corporation of the United States of America under the trade mark Intellitag, and those sold by Texas  
15 Instruments of the United States of America under the trade mark Tagit.

The RFID tags herein may be used in combination and/or integrated with other traditional product labelling methods including visual text, machine-readable text, bar codes and dot codes.

20 In one aspect, the sensor writes the environmental parameter to the memory of the chip.

25 In another aspect, the sensor transmits the environmental parameter to a reader/writer which writes the parameter to the memory of the chip.

30 In a further aspect, the sensor measures plural environmental conditions as plural environmental parameters. The environmental condition is selected from the group consisting of temperature, humidity, pressure, electromagnetic radiation, light, acceleration and chemical concentration.

In another aspect, the writing of the environmental parameter to the memory is continuously or periodically transmittable from the sensor or the reader/writer.

Preferably, the writing of the environmental parameter to the memory is transmittable post-production, post-storage or post-transport of the object. This has the advantage that it reduces the need for a reader/writer in each production, storage and transport container or environment by using centralised reader/writers in each of these areas. Thus environmental parameters are written to the tags at the end of production, storage and transport of the object.

10 In a further aspect, a data processor associated with the sensor or reader/writer processes the environmental parameter data prior to transmitting them to the memory. The data may be processed to determine, for example, the rate of change or the length of exposure to any given environmental parameter. These analysed data may also be written to the chip memory.

15 Preferably, the method additionally comprises reading the memory by transmitting radiofrequency energy from a reader/writer to the radiofrequency identifier. The reading may occur during or post-production, storage or transport of the object.

20 In one aspect, the memory comprises a unique signature data item and the reading step comprises reading the unique signature data item.

25 Preferably, the reading step additionally comprises reading at least one environmental parameter. More preferably, the reading step additionally comprises checking the at least one environmental parameter against a defined compliance criterion.

30 In another aspect, non-compliance with any check results in rejection of the associated object. Non-compliance may alternatively result in a modification of the effective shelf-life or lifetime of the object, which is written to the tag memory.

Thus, for example, the shelf-life of a medicament may be modified depending upon its exposure to pre-defined environmental conditions.

Preferably the method additionally comprises a final reading step involving  
5 reading all environmental parameters in the memory by transmitting radiofrequency energy to the radiofrequency identifier. More preferably, the method additionally comprises checking all environmental parameters against defined full compliance criteria. Most preferably, non-compliance against compliance data results in rejection of the object.

10

In one aspect, the radiofrequency identifier connects to the object.

In another aspect, the object is associated with a container and the radiofrequency identifier connects to the container. Preferably, the container  
15 assists in transport of the object.

Preferably, the sensor and the object or the container are exposed to the same environment. More preferably, the same environment is selected from the group consisting of production facility, warehouse, container transporter and depot.

20

In one aspect, the object is a container for a medicament.

In another aspect, the object is a medical device. Preferably, the medical device is an inhalation device. More preferably, the inhalation device comprises an aerosol canister containing a suspension of medicament in a propellant. More  
25 preferably, the propellant comprises liquefied HFA134a, HFA-227 or carbon dioxide. Most preferably, the aerosol canister comprises a solution of a medicament in a solvent.

Preferably, the inhalation device comprises a cartridge for medicament in dry-powder form. More preferably, the dry-powder cartridge comprises a blister pack.

- 5 Preferably, the medicament is selected from the group consisting of albuterol, salmeterol, fluticasone propionate, ipratropium bromide, beclomethasone dipropionate, salts or solvates thereof and any mixtures thereof.

In another aspect, the object is a container for a food. Preferably, the food is  
10 selected from the group consisting of meat, mycoprotein, milk, cheese, flour, pasta, rice, oil, sugar, confectionery, vegetable, herbal, snack, convenience and fruit foodstuffs.

In a further aspect, the object is a container for a beverage. Preferably, the  
15 beverage is selected from the group consisting of water, milk, coffee, cocoa, tea, fruit, carbonated and alcoholic drinks.

In another aspect, the object is a container for a toiletry. Preferably, the toiletry  
is selected from the group consisting of toothpaste, soap, mouthwash, shampoo,  
20 skin and face cream.

In a further aspect, the object is a container for an electronic component.  
Preferably, the electronic component is selected from the group consisting of  
semi-conductor, integrated circuit chip, fuse and battery.

25 In another aspect, the object is a container for a cleanser. Preferably, the  
cleanser is selected from the group consisting of soap, detergent, enzymic  
preparation and organic solvent.

In a further aspect, the object is a container for a disinfectant. Preferably, the disinfectant is selected from the group consisting of sterilant, antiseptic and bleach.

- 5 In another aspect, the object is a container for a light-sensitive material. Preferably, the light-sensitive material comprises a photographic film.

In a further aspect, the object is a container for a marking material. Preferably, the marking material is selected from the group consisting of toner, ink, dye, pigment, acid and alkali.

10

In another aspect, the object is a container for a covering material. Preferably, the covering material is selected from the group consisting of paint, pigment, dye, corrosion inhibitor, electrical conductor, electrical insulator and static inhibitor.

15

In a further aspect, the object is a container for a diesel- or petrol-based fuel oil.

20

In another aspect, the object is a container for an adhesive. Preferably, the adhesive bonds materials selected from the group consisting of paper, plastic, wood, rubber, glass and metal.

25

In a further aspect, the object is a container for an agrochemical. Preferably, the agrochemical is selected from the group consisting of herbicide, insecticide, fungicide, rodenticide, nematocide, acaracide and plant growth regulator.

30

In another aspect, the object is a container for a contraceptive. Preferably the contraceptive is either a contraceptive device or a contraceptive drug. More preferably, the contraceptive device is selected from the group consisting of condom, diaphragm, sponge and coil. More preferably, the contraceptive drug

is selected from the group consisting of spermicide, estrogen, ethinyl estradiol, progesterone, levonorgestrel and norgestrel.

In a further aspect, the object is a container for a biological material. Preferably, the biological material is selected from the group consisting of polynucleotide, peptide, enzyme, hormone, protein, cell line and tissue. More preferably, the biological material is a mammalian or human organ. More preferably, the biological material is a plant seed derived from a monocotyledonous or dicotyledonous plant. Optionally, the biological material is an animal.

10

In one aspect, the antenna is capable of transmitting or receiving radiofrequency energy having a frequency of from 50 KHz to 2.5 GHz. Preferably, the antenna is adapted to transmit or receive radiofrequency energy having a frequency of 125 KHz. More preferably, the antenna is adapted to transmit or receive radiofrequency energy having a frequency of 13.56 MHz. More preferably, the antenna is adapted to transmit or receive radiofrequency energy having a frequency of 2.4 GHz.

15

In another aspect, the radiofrequency identifier is on a carrier suitable for mounting to the object or the container therefor. The carrier is preferably a flexible label, rigid disc or a rectangular block, although other shapes and forms of carrier are envisaged.

20

In a further aspect, the carrier is mouldable to the object or the container.

25

Preferably, the carrier encases the radiofrequency identifier. More preferably, the carrier forms a hermetic seal for the radiofrequency identifier. More preferably, the carrier comprises an insulating material such as a glass material, paper material or organic polymeric material.

30

In another aspect, the integrated circuit chip has plural memory areas thereon. The plural memory areas can be selected from a read only memory area, a write only memory area, a read/write memory area, a one time programmable memory area, a pre-set, non-amendable memory area and any mixtures thereof.

- 5 Preferably, any memory area contains data in encrypted form and/or is password protected.

Preferably, the reader/writer is capable of following an anti-contention protocol and reading multiple radiofrequency identifiers simultaneously by differentiating 10 between individual radiofrequency identifiers within the same antenna field. More preferably, the reader/writer is capable of writing to a plurality of individual radiofrequency identifiers simultaneously.

- 15 In one aspect, the method additionally comprises transferring each environmental data item read from the memory or transmitted from the reader/writer to an electronic data management system comprising a data memory for storage of data; a microprocessor for performing operations on the data; and a signal output for outputting a signal relating to the data or the outcome of an operation on the data. The electronic data management system may be connected to a 20 networked computer system by any suitable method including a hard-wired link or a wireless communications link such as one based on infra red or radiofrequency links.

- 25 In another aspect, the method additionally comprises transferring each environmental data item read from the memory to a distributed electronic data management system comprising plural electronic data collectors, each comprising a data memory for storage of data; a microprocessor for performing operations on the data; and a signal output for outputting a signal relating to the data or the outcome of an operation on the data, wherein the plural electronic data collectors are in network relationship to form the distributed electronic data 30 management system.

In one aspect, the electronic data collectors may comprise what is known in the art as 'field devices' which are used for local data collection. Each 'field device' may be capable of wireless communication to the other or to the electronic data management system.

5

In another aspect, the electronic data management system forms part of a robotics system.

Preferably, the method additionally comprises a communicator for wireless communication with a gateway to a network computer system to enable transfer of data between the network computer system and the electronic data management system. More preferably, the method enables two-way transfer of data between the network computer system and the electronic data management system.

10

The communication may be via radiofrequency or optical signals.

In one aspect, the communicator communicates directly with the gateway.

20 In another aspect, the communicator communicates with the gateway via a second communications device. Preferably, the second communications device is a telecommunications device, more preferably a cellular phone or pager. Preferably, the communicator communicates with the second communications device using spread spectrum radiofrequency signals. A suitable spread spectrum protocol is the Bluetooth (trademark) standard which employs rapid (e.g. 1600 times a second) hopping between plural frequencies (e.g. 79 different frequencies). The protocol may further employ multiple sending of data bits (e.g. sending in triplicate) to reduce interference.

25

30 Preferably, the data are communicable between the network computer system and the electronic data management system in encrypted form. All suitable

methods of encryption or partial encryption are envisaged. Password protection may also be employed.

In one aspect, the network computer system comprises a public access network  
5 computer system. The Internet is one suitable example of a public access networked computer system, wherein the gateway can be any suitable gateway thereto including gateways managed by an Internet service provider. The public access network computer system may also form part of a telecommunications system, which may itself be either a traditional copper wire system, a cellular  
10 system or an optical network.

In another aspect, the network computer system comprises a private access network computer system and the gateway is a secure gateway. The private access network system may, for example, comprise an intranet or extranet  
15 maintained by a medicament manufacturer. The secure gateway may, for example, include password protection; a firewall; and suitable encryption means.

The method preferably comprises communicating with a user-specific network address in the network computer system. More preferably, the user-specific  
20 network address is selected from the group consisting of a web-site address, an e-mail address and a file transfer protocol address.

In another aspect of the present invention, there is provided a system for tracking environmental exposure of an object according to the method hereinbefore  
25 described, comprising a radiofrequency identifier comprising an antenna for transmitting and receiving radiofrequency energy; and an integrated circuit chip connecting with said antenna, said chip having a memory; a physically separate sensor capable of measuring an environmental condition as an environmental parameter and writing said environmental parameter to the memory of the chip by  
30 transmitting radiofrequency energy thereto.

In one aspect, the sensor transmits the environmental parameter to the memory of the chip.

5 In another aspect, the sensor transmits the environmental parameter to a reader/writer which writes the parameter to the memory of the chip.

In a further aspect, the system additionally comprises a reader/writer for reading data from the radiofrequency identifier by transmitting radiofrequency energy thereto and receiving radiofrequency energy therefrom.

10 In another aspect, the system additionally comprises an electronic data management system and a network computer system according to the method as hereinbefore described.

15 Embodiments of methods according to the invention will now be described with reference to the accompanying drawings in which:

Figure 1a is a diagram of a radiofrequency identification (RFID) tag mounted on a rectangular shaped carrier.

20 Figure 1b is a diagram of a RFID tag mounted on a disc shaped carrier.

Figure 2 is a schematic representation of the memory structure of the RFID tag.

25 Figure 3 is a diagram of a metered dose inhaler with a disc shaped RFID tag attached to the aerosol container.

Figure 4 is a diagram of a RFID tag attached to a container receiving environmental data from a sensor.

Figure 5 is a schematic diagram of RFID tags, attached to containers, receiving environmental data from a sensor within a closed environment.

Figure 6 is a flow diagram of a method of monitoring environmental exposure

5 using RFID tags.

Figure 7 is a schematic representation of a system employing a method of tracking environmental exposure using RFID tags.

10 The basic components of an RFID tag are shown in Figures 1a and 1b. The tag comprises a memory chip 1 which is capable of storing, transmitting and receiving information and an antenna 5. Data can be received by, or transmitted from, the chip via antenna 5 which is connected to the chip. The antenna 5, is capable of receiving or transmitting radiofrequency energy over a wide bandwidth, ranging from 50 KHz to 2.5 GHz. The tags 10 are mounted on a rectangular 15 (Figure 1a) or disc 20 (Figure 1b) shaped carrier. The carrier, which generally comprises an insulating material such as glass, may take several forms such as a flexible label (Figure 1a), a rectangular block or a rigid disc (Figure 1b).

15

20 Figure 2 is a schematic representation of the memory structure of the RFID chip 101. Such tags are divided into unique blocks, typically numbering sixteen in total, with data being stored in non-volatile memory EEPROM, the EEPROM having a memory capacity of 512 bits with each block consisting of 4 bytes.

25

However, for the sake of simplicity, in the illustration shown in Figure 2 the tag is divided into three blocks 102-104 only.

30

The first block 102 contains unique tag identifiers such as serial numbers, this information being in a read only format and being encoded on the tag at the time of manufacture such that this information cannot be altered once set.

The second block 103 permits write access conditions to be determined for the third block 104, for example to allow read and write access to the remaining blocks. This block may be considered a 'secret area' in that access requires mutual authentication and enciphered data communications are used in this  
5 area. The second block 103 may be made read only once information has been written to it, i.e. it may become one time programmable.

The third block 104 can be considered to be a 'user' or 'public' area in that it may be programmed, by block two 103, such that information may be read from or  
10 written to it. This is generally the format in operation, information being read from and written to this area. Access can be password protected and data may be in encrypted format to enhance security.

In use, information from block one 102 (i.e. the unique serial number) will  
15 generally be used to identify the tag at each stage in a pre-determined process. Environmental data will be transmitted from a separate sensor (not shown) to block three 104, where it can be stored and accessed by a reader (not shown). These environmental data can be monitored from a localised or centralised workstation and checked against defined criteria.  
20

Figure 3 depicts a standard metered-dose inhaler, comprising housing 230, mouthpiece 235 and aerosol container 238. A RFID tag mounted on a disc shaped carrier 220 is attached to the aerosol container 238. It will be understood from Figure 1 that different shaped carriers may be used to affix the  
25 RFID tag to the housing, the aerosol container or the mouthpiece. Attachment of the disc shaped carrier 220 to the aerosol container 238 may be by adhesive, hermetic or welding means.

A RFID tag 310 is shown attached to a container 340 for an object in Figure 4.  
30 The diagram depicts a sensor 350, located in the same environment as the container 340, transmitting environmental data 355 to the tag 310. The

environmental data may for example be temperature or pressure data measured by the sensor. These data will be stored in the memory of the tag 310 and can be accessed on energising by a reader/writer (not shown).

- 5       Figure 5 illustrates a sensor 450 simultaneously transmitting environmental data 455 to individual RFID tags 410 which are attached to a number of containers 440 stored within a much larger container 460. Environmentally sensitive products (not shown), such as medicaments, may be stored within the containers 440. The larger container may, for example, be a cargo/freight  
10      container used for the transport or storage of goods.

A flow diagram of a method for monitoring or tracking environmental exposure through the lifetime of an object until the point of sales is shown in Figure 6. The method begins by selecting the object 561 to be tagged with the RFID tag. An  
15      association between the object and the tag is made 562 and appropriate information, such as a time/date stamp, is written to the tag chip. The production process then commences 563 and a separate sensor, located within the same environment as the object, continuously measures environmental conditions (E1, E2, ...En) 564 and writes these as environmental parameters 565 to the tag chip  
20      either continuously or at defined intervals throughout production. The environmental data may be analysed by a microprocessor associated with the sensor and the analysed data also transmitted to the tag chip. At the end of the production process the environmental data are read 566 on energising by a reader/writer and checked 567 against defined criteria: if not compliant 568 the  
25      object is rejected 569; if compliant, however, storage commences 570.

During storage another sensor measures and may analyse environmental conditions (E1, E2,...En) 571, writing these data to the tag chip either  
30      continuously or at defined intervals throughout the storage period 572. At the end of this time, the tag is read 573 on energising by a reader/writer and compliance checked against defined environmental exposure criteria 574. Once

again, non-compliance 575 results in rejection 576 of the object, whilst compliance permits transportation 577 of the object.

Throughout transportation, which may take the form of road, rail, sea or air  
5 freight, a localised sensor located within the same environment as the object measures and may analyse environmental conditions (E1, E2, ...En) 578, writing 579 these parameters to the tag chip. These data are read at the end of the transportation process 580 on energising by a reader/writer and checked 581 against defined environmental criteria, failure 582 leading to rejection 583 or  
10 recall by the manufacturer of the object. If compliant 584, delivery of the object is accepted for a further period of storage or sales.

A schematic representation of a system employing a method for monitoring environmental exposure is shown in Figure 7. The diagram illustrates a  
15 simplified process from manufacture through to sales.

RFID tags 610 are associated with containers 640 for objects during production. Environmental conditions are measured by a separate sensor S1, located within the same environment 660 as the containers, and are written 665 to the tag  
20 chips as environmental parameters. The environmental data may also be analysed by a microprocessor associated with the sensor and the analysed data transmitted to the tag chip. At the end of production the environmental data are read 666 for each container 640 on energising by reader/writer R1 and checked for compliance against defined environmental exposure criteria. Failure to  
25 comply results in rejection 669 of the container while compliance leads to storage of the goods.

Sensor S2 transmits environmental data 672 to the tag chips throughout storage. A microprocessor associated with the sensor S2 may analyse the environmental  
30 data prior to transmitting 672 processed data to the tag chips. At the end of the storage period these data are read 673 for each container on energising by

reader/writer R2. Compliance against defined environmental criteria is then assessed, failure leading to rejection of the container 676 while compliance results in transportation of the goods.

- 5 During transport, environmental data measured by sensor S3 is continuously transmitted 679 to the tag chips. A microprocessor associated with the sensor S3 may analyse these data and transmit these, in addition to the 'raw' data, to the tag chips. These data are read 680 for each container on energising by reader/writer R3 on arrival at the destination (e.g. a warehouse) and checked for 10 compliance against defined environmental criteria. A further period of storage will now take place if the data pass the compliance check, otherwise the containers will be rejected 683 or recalled to the manufacturer.

- 15 Local sensor S4 measures and transmits 685 environmental data to the tag chips during the second storage period. Once again, data may be analysed by a microprocessor associated with the sensor S4 and transmitted to the tag chips. At the end of this time each tag is read 686 on energising by reader/writer R4 and the environmental data compared against defined criteria. Only containers with data which satisfy these 20 criteria will be accepted for sales, failure to comply resulting in rejection 687 or recall of the containers.

- In the diagram the process is controlled by an electronic data management system 690 which is capable of receiving information from the reader R1 to R4. 25 A robotics system (not shown) may form part of this system during the production and storage processes. The system will carry out the compliance checks against environmental criteria, notifying operators to pass or reject the containers.
- 30 The system may also be connected to a networked computer system 695 to allow transfer of data between both systems, preferably the data being in

encrypted format. The networked computer system may be a publicly accessible system, such as the Internet, or a privately accessible system such as an intranet or extranet.

- 5 It will be understood that variants of the system described above are possible. Thus a system whereby separate sensors within the Production, Storage and Transport environments record environmental data either continuously or at regular intervals and then transfer the data to a reader/writer at the end of each process, is envisaged. In such a system the reader/writer would transmit the  
10 environmental data to an electronic data management system and/or to the tag memories at the end of each process. The tags would then be read and compliance assessed as previously described, failure to satisfy predefined environmental criteria resulting in rejection whilst compliant goods would move on to the next stage in the process. The advantage of such a system is that  
15 there is no need for the sensors to have the ability to write data to the RFID tags in each environment, the system simply relying on centralised readers/writers present in the production/storage and delivery areas.

The system of the invention is in one aspect suitable for monitoring  
20 environmental exposure of medicament such as those for the treatment of ulcers, e.g., omeprazole, lansoprazole, lipid levels, e.g., simvastatin, atorvastatin, hypertension, e.g., amlodipine, depression, e.g. fluoxetine, paroxetine, sertraline, allergies, e.g., loratadine, and psychosis, e.g., olanzapine.

- 25 In particular, the system of the invention is particularly suitable for monitoring exposure of medicament for the treatment of respiratory disorders. Appropriate medicaments may thus be selected from, for example, analgesics, e.g., codeine, dihydromorphine, ergotamine, fentanyl or morphine; anginal preparations, e.g., diltiazem; antiallergics, e.g., cromoglycate, ketotifen or  
30 nedocromil; antiinfectives e.g., cephalosporins, penicillins, streptomycin, sulphonamides, tetracyclines and pentamidine; antihistamines, e.g.,

methapyrilene; anti- inflammatories, e.g., beclomethasone dipropionate, fluticasone propionate, flunisolide, budesonide, rofleponide, mometasone furoate, ciclesonide or triamcinolone acetonide; antitussives, e.g., noscapine; bronchodilators, e.g., albuterol, salmeterol, ephedrine, adrenaline, fenoterol, 5 formoterol, isoprenaline, metaproterenol, phenylephrine, phenylpropanolamine, pirbuterol, reproterol, rimiterol, terbutaline, isoetharine, tulobuterol or 4-hydroxy-7-[2-[[2-[[3-(2-phenylethoxy)propyl]sulfonyl]ethyl]amino]ethyl]-2(3H)-benzothiazolone; diuretics, e.g., amiloride; anticholinergics, e.g., ipratropium, tiotropium, atropine or oxitropium; hormones, e.g., cortisone, hydrocortisone or 10 prednisolone; xanthines, e.g., aminophylline, choline theophyllinate, lysine theophyllinate or theophylline; therapeutic proteins and peptides, e.g., insulin or glucagon; vaccines, diagnostics, and gene therapies. It will be clear to a person skilled in the art that, where appropriate, the medicaments may be used in the form of salts, (e.g., as alkali metal or amine salts or as acid addition salts) or as 15 esters (e.g., lower alkyl esters) or as solvates (e.g., hydrates) to optimise the activity and/or stability of the medicament and/or to minimise the solubility of the medicament in the propellant.

Preferred medicaments are selected from albuterol, salmeterol, ipratropium bromide, fluticasone propionate and beclometasone dipropionate and salts or solvates thereof, e.g., the sulphate of albuterol and the xinafoate of salmeterol.

Medicaments can also be delivered in combinations. Preferred formulations containing combinations of active ingredients contain salbutamol (e.g., as the free base or the sulphate salt) or salmeterol (e.g., as the xinafoate salt) in 25 combination with an antiinflammatory steroid such as a beclomethasone ester (e.g., the dipropionate) or a fluticasone ester (e.g., the propionate). A particularly preferred combination comprises salmeterol xinafoate salt and fluticasone propionate.

It will be understood that the present disclosure is for the purpose of illustration only and the invention extends to modifications, variations and improvements thereto.

- 5      The application of which this description and claims form part may be used as a basis for priority in respect of any subsequent application. The claims of such subsequent application may be directed to any feature or combination of features described therein. They may take the form of product, method or use claims and may include, by way of example and without limitation, one or more of the following claims:
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**Claims**

1. A method for tracking environmental exposure of an object comprising
  - 5 selecting said object;
  - associating a radiofrequency identifier with the object, the radiofrequency identifier comprising
  - 10 an antenna for transmitting or receiving radiofrequency energy; and
  - an integrated circuit chip connecting with said antenna, said chip having
  - 15 a memory;
  - exposing the object to an environmental condition;
  - measuring said environmental condition as an environmental parameter with a sensor physically separate from said radiofrequency identifier; and
  - 20 writing said environmental parameter to the memory of the chip by transmitting radiofrequency energy thereto.
2. A method according to claim 1, wherein said sensor writes the environmental parameter to said memory of the chip.
3. A method according to claim 1, wherein the sensor transmits the environmental parameter to a reader/writer which writes said parameter to the memory of the chip.

4. A method according to any of claims 1 to 3, wherein the sensor measures plural environmental conditions as plural environmental parameters.

5. A method according to any of claims 1 to 4, wherein said environmental condition is selected from the group consisting of temperature, humidity, pressure, electromagnetic radiation, light, acceleration and chemical concentration.

10 6. A method according to any of claims 1 to 5, wherein said writing of the environmental parameter to the memory is continuously or periodically transmittable from the sensor or said reader/writer.

15 7. A method according to any of claims 1 to 6, wherein the writing of the environmental parameter to the memory is transmittable post-production, storage or transport of the object.

20 8. A method according to any of claims 1 to 7, wherein a data processor associated with the sensor or reader/writer processes the environmental parameter data prior to transmitting them to the memory.

9. A method according to any of claims 1 to 8, additionally comprising reading the memory by transmitting radiofrequency energy from a reader/writer to the radiofrequency identifier.

25 10. A method according to claim 9, wherein said reading occurs during or post-production, storage or transport of the object.

30 11. A method according to any of claims 1 to 10, wherein the memory comprises a unique signature data item and said reading step comprises reading said unique signature data item.

12. A method according to any of claims 9 to 11, wherein the reading step additionally comprises reading at least one environmental parameter.
- 5 13. A method according to claim 12, additionally comprising checking said at least one environmental parameter against a defined compliance criterion.
14. A method according to claim 13, wherein non-compliance with any check results in rejection of the associated object.
- 10 15. A method according to any of claims 1 to 14, additionally comprising a final reading step involving reading all environmental parameters in the memory by transmitting radiofrequency energy to the radiofrequency identifier.
- 15 16. A method according to claim 15, additionally comprising checking all environmental parameters against defined full compliance criteria.
17. A method according to claim 16, wherein non-compliance against compliance data results in rejection of the object.
- 20 18. A method according to any of claims 1 to 17, wherein the radiofrequency identifier connects to the object.
- 25 19. A method according to any of claims 1 to 18, wherein the object is associated with a container and the radiofrequency identifier connects to said container.
20. A method according to claim 19, wherein the container assists in transport of the object.

21. A method according to any of claims 18 to 20, wherein the sensor and the object or the container are exposed to the same environment.

5 22. A method according to claim 21, wherein said same environment is selected from the group consisting of production facility, warehouse, container transporter and depot.

23. A method according to any of claims 1 to 22, wherein the object is a container for a medicament.

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24. A method according to any of claims 1 to 22, wherein the object is a medical device.

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25. A method according to claim 24, wherein the medical device is an inhalation device.

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26. A method according to claim 25, wherein said inhalation device comprises an aerosol canister containing a suspension of medicament in a propellant.

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27. A method according to claim 26, wherein said propellant comprises liquified HFA134a, HFA-227 or carbon dioxide.

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28. A method according to claim 26, wherein said aerosol canister comprises a solution of a medicament in a solvent.

29. A method according to claim 25, wherein the inhalation device comprises a cartridge for medicament in dry-powder form.

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30. A method according to claim 29, wherein said dry-powder cartridge comprises a blister pack.

31. A method according to any of claims 28 to 30, wherein said medicament is selected from the group consisting of albuterol, salmeterol, fluticasone propionate, ipratropium bromide, beclomethasone dipropionate, salts or solvates thereof and any mixtures thereof.
- 5
32. A method according to any of claims 1 to 22, wherein the object is a container for a food.
- 10 33. A method according to claim 32, wherein said food is selected from the group consisting of meat, mycoprotein, milk, cheese, flour, pasta, rice, oil, sugar, confectionery, vegetable, herbal, snack, convenience and fruit foodstuffs.
- 15 34. A method according to any of claims 1 to 22, wherein the object is a container for a beverage.
35. A method according to claim 34, wherein said beverage is selected from the group consisting of water, milk, coffee, cocoa, tea, fruit, carbonated and alcoholic drinks.
- 20 36. A method according to any of claims 1 to 22, wherein the object is a container for a toiletry.
- 25 37. A method according to claim 36, wherein said toiletry is selected from the group consisting of toothpaste, soap, mouthwash, shampoo, skin and face cream.
38. A method according to any of claims 1 to 22, wherein the object is a container for an electronic component.

39. A method according to claim 38, wherein said electronic component is selected from the group consisting of semi-conductor, integrated circuit chip, fuse and battery.
- 5 40. A method according to any of claims 1 to 22, wherein the object is a container for a cleanser.
41. A method according to claim 40, wherein said cleanser is selected from the group consisting of soap, detergent, enzymic preparation and organic solvent.
- 10 42. A method according to any of claims 1 to 22, wherein the object is a container for a disinfectant.
- 15 43. A method according to claim 42, wherein said disinfectant is selected from the group consisting of sterilant, antiseptic and bleach.
44. A method according to any of claims 1 to 22, wherein the object is a container for a light-sensitive material.
- 20 45. A method according to claim 44, wherein said light-sensitive material comprises a photographic film.
46. A method according to any of claims 1 to 22, wherein the object is a container for a marking material.
- 25 47. A method according to claim 46, wherein said marking material is selected from the group consisting of toner, ink, dye, pigment, acid and alkali.
- 30 48. A method according to any of claims 1 to 22, wherein the object is a container for a covering material.

49. A method according to claim 48, wherein said covering material is selected from the group consisting of paint, pigment, dye, corrosion inhibitor, electrical conductor, electrical insulator and static inhibitor.

5 50. A method according to any of claims 1 to 22, wherein the object is a container for a diesel- or petrol-based fuel oil.

51. A method according to any of claims 1 to 22, wherein the object is a container for an adhesive.

10 52. A method according to claim 51, wherein said adhesive bonds materials selected from the group consisting of paper, plastic, wood, rubber, glass and metal.

15 53. A method according to any of claims 1 to 22, wherein the object is a container for an agrochemical.

20 54. A method according to claim 53, wherein said agrochemical is selected from the group consisting of herbicide, insecticide, fungicide, rodenticide, nematocide, acaricide and plant growth regulator.

55. A method according to any of claims 1 to 22, wherein the object is a container for a contraceptive.

25 56. A method according to claim 55, wherein said contraceptive is either a contraceptive device or a contraceptive drug.

57. A method according to claim 56, wherein said contraceptive device is selected from the group consisting of condom, diaphragm, sponge and coil.

58. A method according to claim 56, wherein said contraceptive drug is selected from the group consisting of spermicide, estrogen, ethinyl estradiol, progesterone, levonorgestrel and norgestrel.

5 59. A method according to any of claims 1 to 22, wherein the object is a container for a biological material.

10 60. A method according to claim 59, wherein said biological material is selected from the group consisting of polynucleotide, peptide, enzyme, hormone, protein, cell line and tissue.

61. A method according to claim 59, wherein the biological material is a mammalian or human organ.

15 62. A method according to claim 59, wherein the biological material is a plant seed derived from a monocotyledonous or dicotyledonous plant.

63. A method according to claim 59, wherein the biological material is an animal.

20 64. A method according to any of claims 1 to 63, wherein the antenna is capable of transmitting or receiving radiofrequency energy having a frequency of from 50 KHz to 2.5 GHz.

25 65. A method according to claim 64, wherein the antenna is adapted to transmit or receive radiofrequency energy having a frequency of 125 KHz.

66. A method according to claim 64, wherein the antenna is adapted to transmit or receive radiofrequency energy having a frequency of 13.56 MHz.

67. A method according to claim 64, wherein the antenna is adapted to transmit or receive radiofrequency energy having a frequency of 2.4 GHz.
68. A method according to any of claims 1 to 67, wherein the  
5 radiofrequency identifier is on a carrier suitable for mounting to the object or the container therefor.
69. A method according to claim 68, wherein said carrier is a flexible label.
- 10 70. A method according to claim 68, wherein the carrier is a rigid disc.
71. A method according to claim 68, wherein the carrier is a rectangular block.
- 15 72. A method according to claim 68, wherein the carrier is mouldable to the object or the container.
73. A method according to claim 68 to 72, wherein the carrier encases the  
radiofrequency identifier.
- 20 74. A method according to claim 73, wherein the carrier forms a hermetic seal for the radiofrequency identifier.
75. A method according to any of claims 68 to 74, wherein the carrier  
25 comprises an insulating material.
76. A method according to claim 75, wherein said insulating material comprises a glass material, paper material or organic polymeric material.
- 30 77. A method according to any of claims 1 to 76, wherein the integrated circuit chip has plural memory areas thereon.

78. A method according to claim 77, wherein any memory area contains data in encrypted form.

5 79. A method according to any of claims 1 to 78, additionally comprising transferring the environmental data items read from the memory or transmitted from the reader/writer to an electronic data management system comprising

a data memory for storage of data;

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a microprocessor for performing operations on said data; and

a signal output for outputting a signal relating to the data or the outcome of an operation on the data.

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80. A method according to any of claims 1 to 78, additionally comprises transferring the environmental data items read from the memory or transmitted from the reader/writer to a distributed electronic data management system comprising plural electronic data collectors, each comprising

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a data memory for storage of data;

a microprocessor for performing operations on said data; and

25

a signal output for outputting a signal relating to the data or the outcome of an operation on the data,

wherein said plural electronic data collectors are in network relationship to form said distributed electronic data management system.

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81. A method according to either of claims 79 or 80, wherein the electronic data management system forms part of a robotics system.

5 82. A method according to any of claims 79 to 81, additionally comprising a communicator for wireless communication with a gateway to a network computer system to enable transfer of data between the network computer system and the electronic data management system.

10 83. A method according to claim 82, enabling two-way transfer of data between the network computer system and the electronic data management system.

15 84. A method according to either of claims 82 or 83, wherein said data are communicable between the network computer system and the electronic data management system in encrypted form.

85. A method according to any of claims 82 to 84, wherein the network computer system comprises a public access network computer system.

20 86. A method according to any of claims 82 to 84, wherein the network computer system comprises a private access network computer system and the gateway is a secure gateway.

25 87. A method according to any of claims 82 to 86, comprising communicating with a user-specific network address in the network computer system.

30 88. A method according to claim 87, wherein the user-specific network address is selected from the group consisting of a web-site address, an e-mail address and a file transfer protocol address.

89. A system for tracking environmental exposure of an object according to the method of any of claims 1 to 78, comprising

a radiofrequency identifier comprising

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an antenna for transmitting and receiving radiofrequency energy; and

an integrated circuit chip connecting with said antenna, said chip having a memory;

10

a physically separate sensor capable of measuring an environmental condition as an environmental parameter;

and writing said environmental parameter to said memory of said chip by

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transmitting radiofrequency energy thereto.

90. A system according to claim 89, wherein the sensor transmits the environmental parameter to the memory of the chip.

20

91. A system according to claim 89, wherein the sensor transmits the environmental parameter to a reader/writer which writes the parameter to the memory of the chip.

25

92. A system according to any of claims 89 to 91, additionally comprising a reader/writer for reading data from the radiofrequency identifier by transmitting radiofrequency energy thereto and receiving radiofrequency energy therefrom.

93. A system according to claim 92, additionally comprising an electronic data management system and a network computer system according to the method of any of claims 79 to 88.

30

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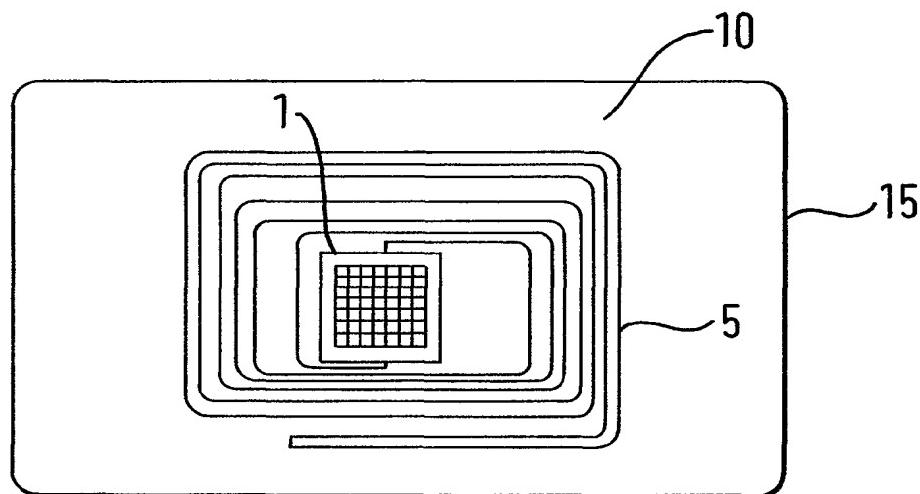


FIG. 1a

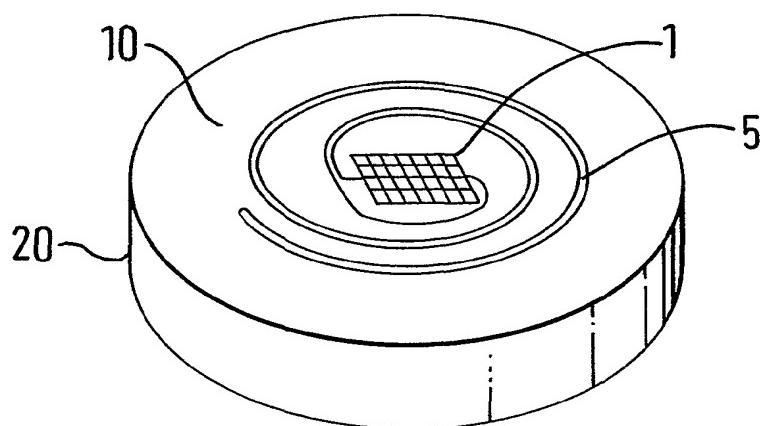


FIG. 1b

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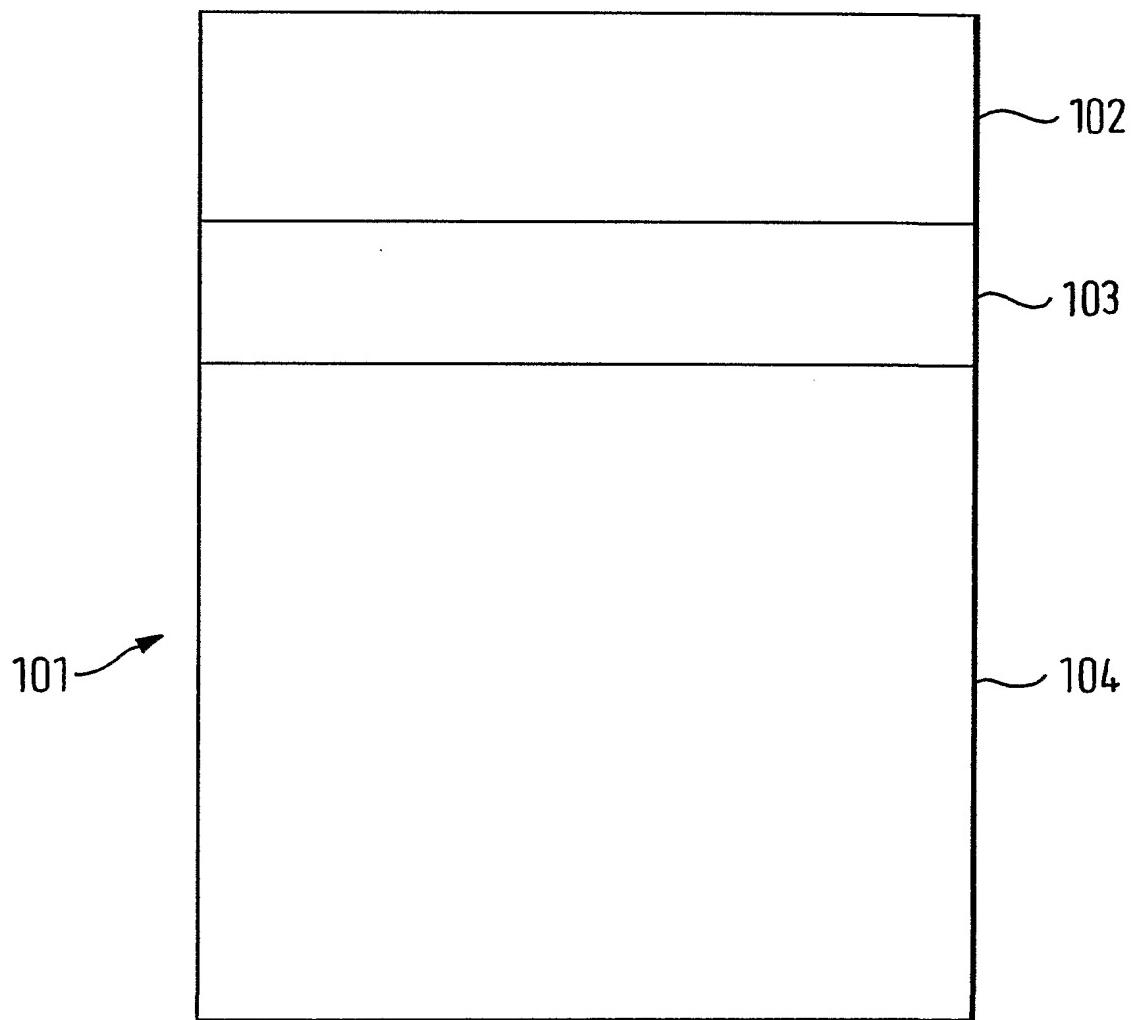


FIG. 2

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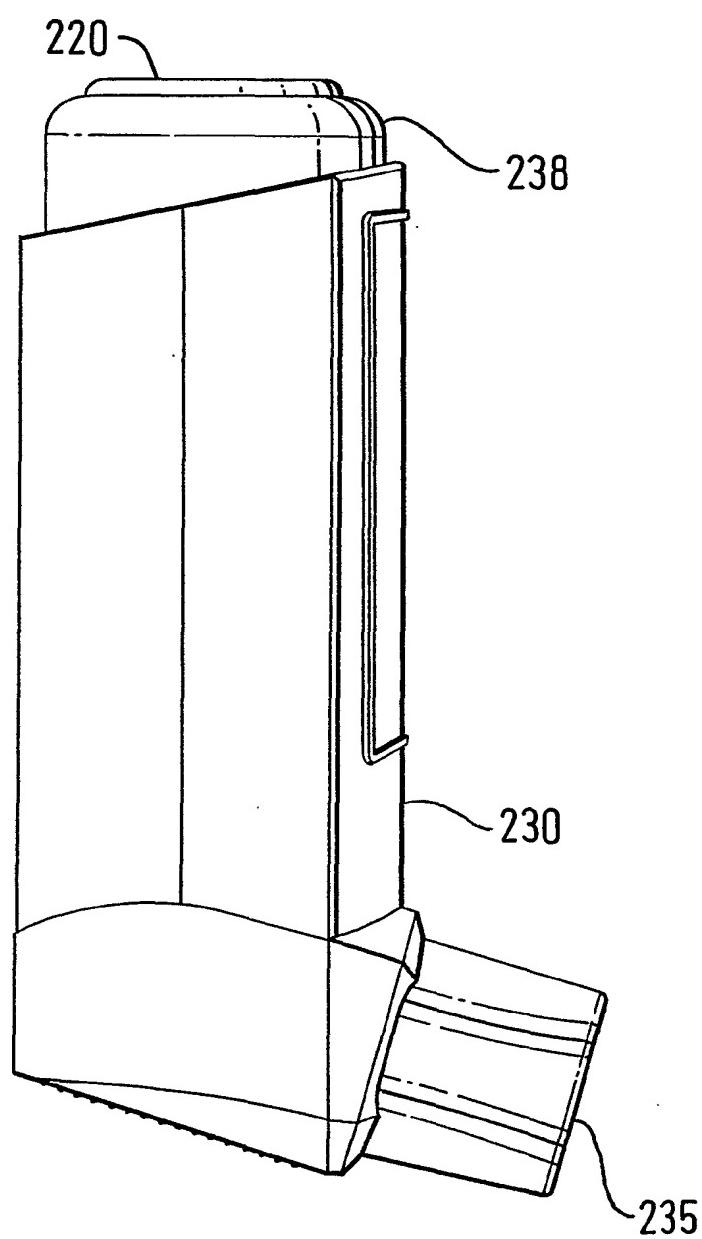


FIG. 3

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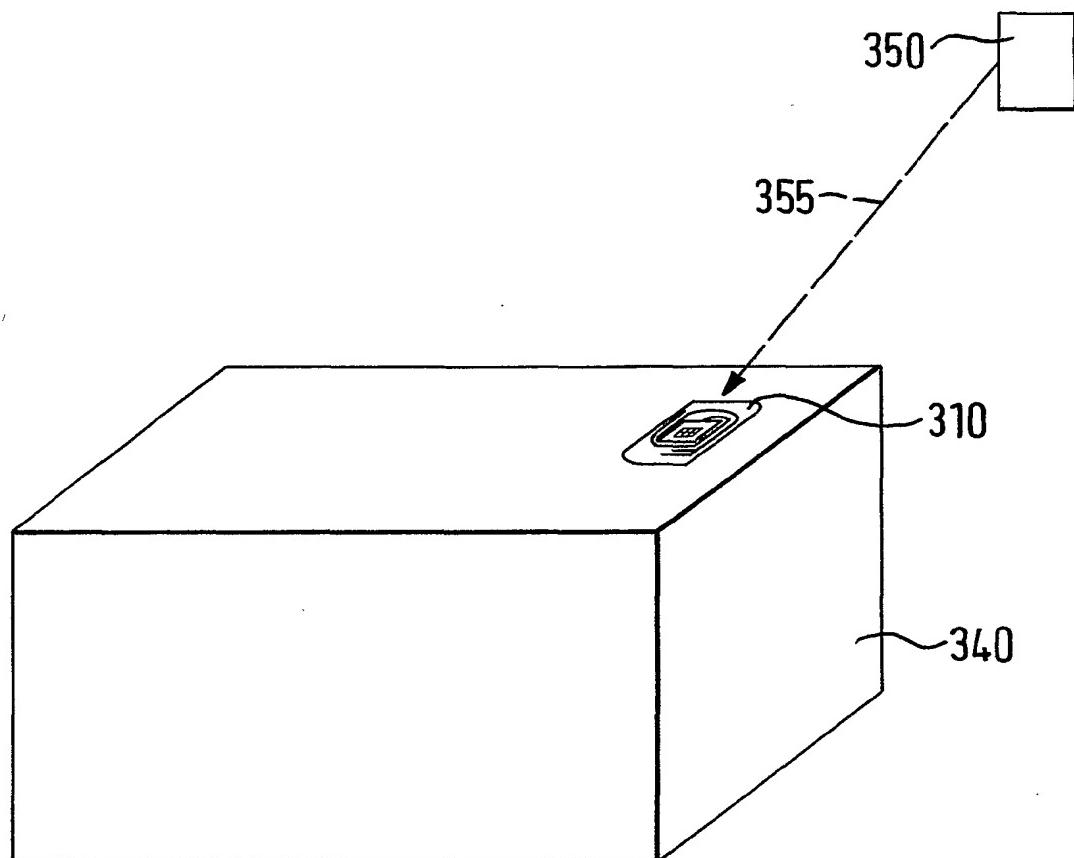


FIG. 4

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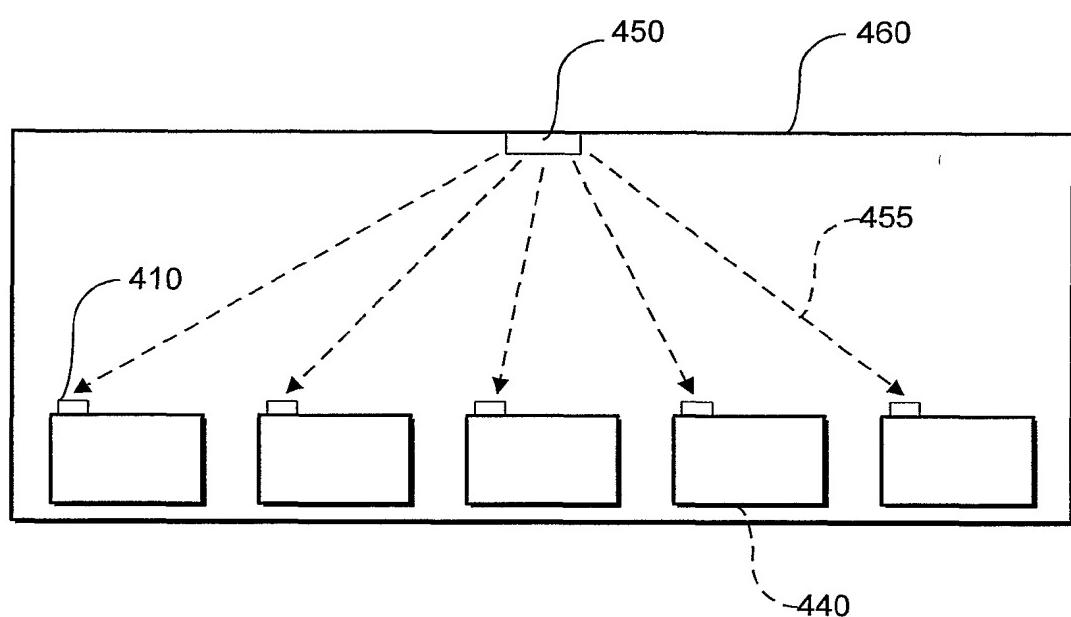
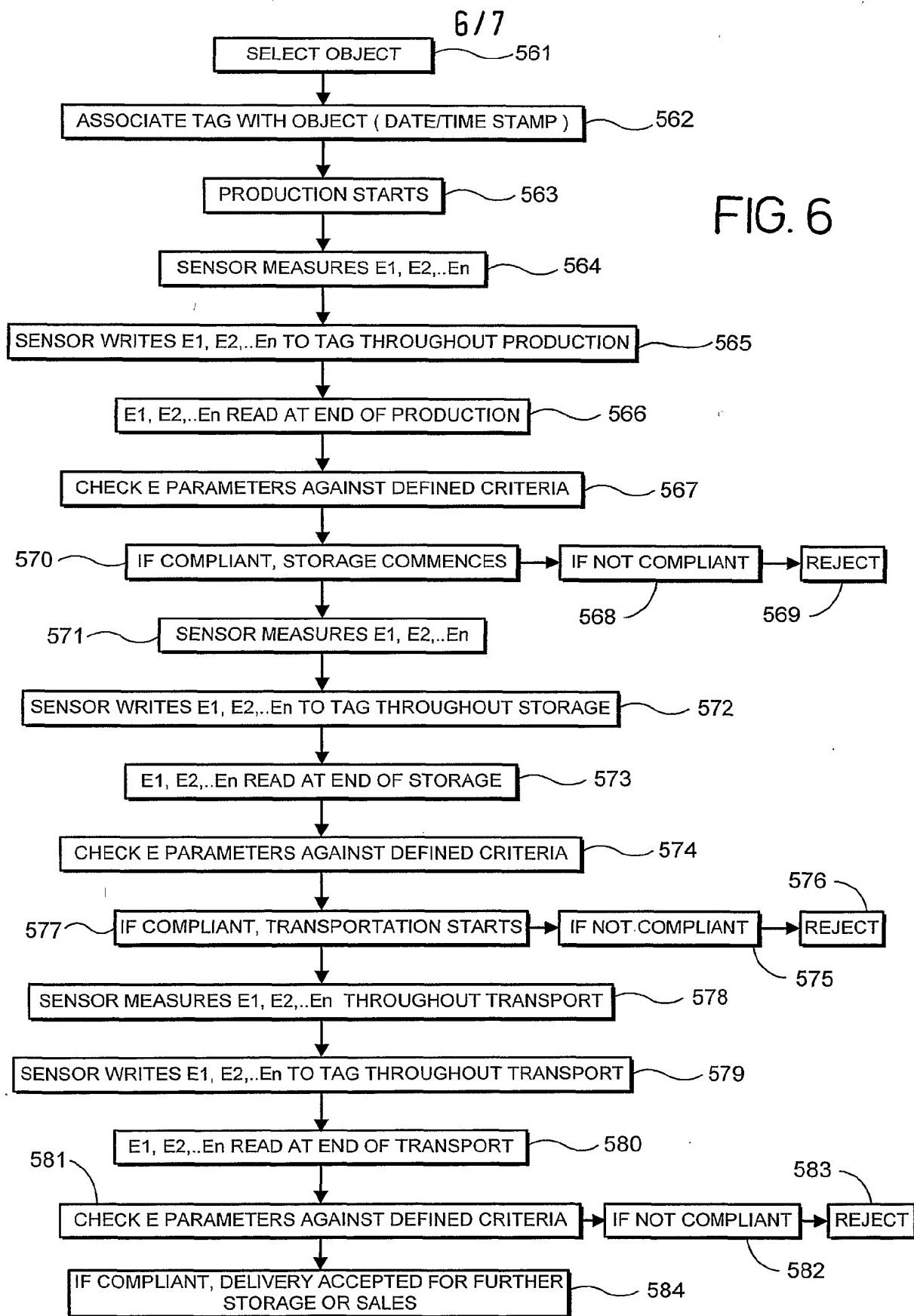


FIG. 5



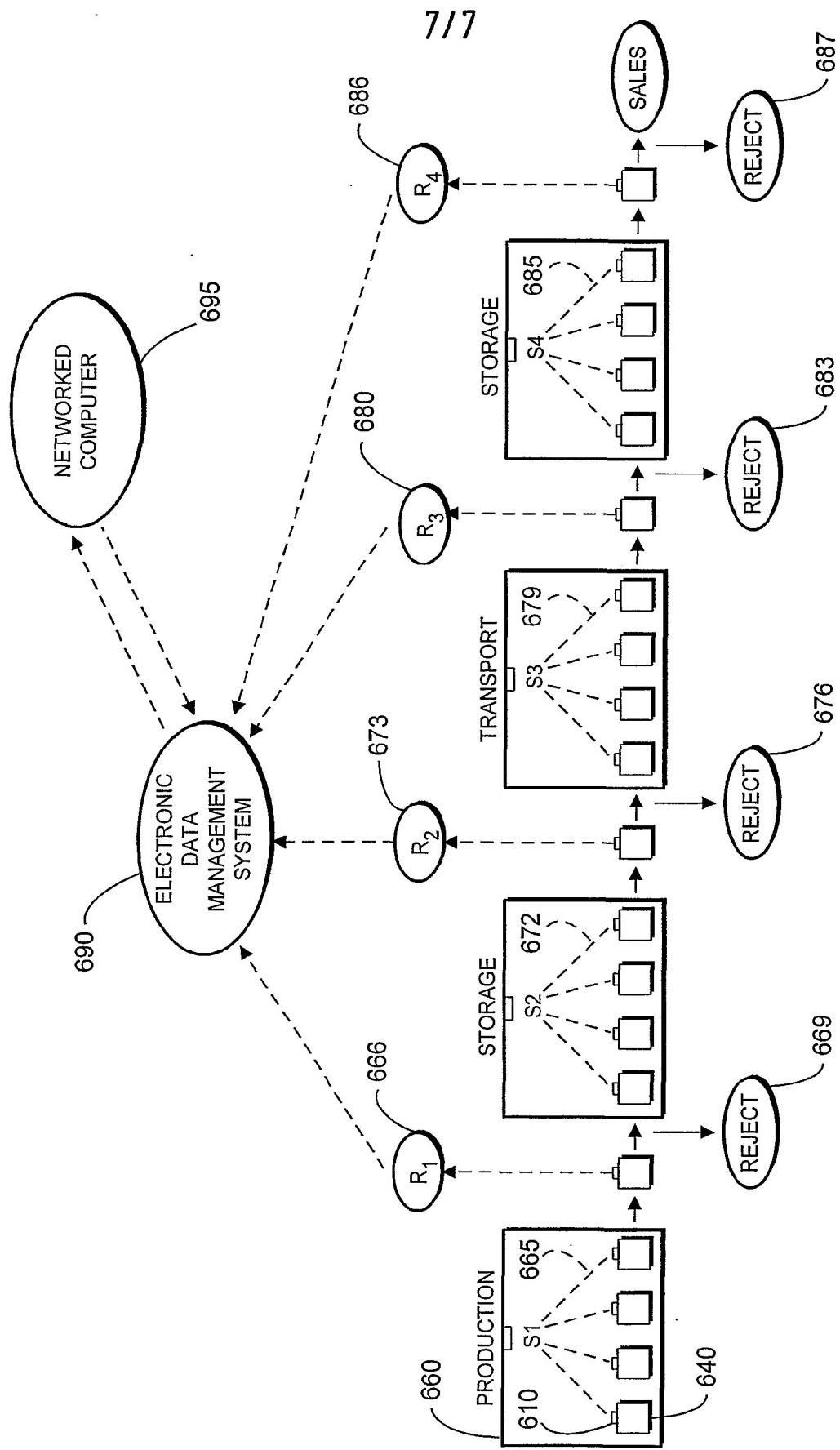


FIG. 7

# INTERNATIONAL SEARCH REPORT

Intern. Application No

PCT/EP 01/04972

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC 7 G08C17/02

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 G08C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, INSPEC

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category <sup>a</sup>	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 892 441 A (WEIMAR JAMES H ET AL) 6 April 1999 (1999-04-06) column 16, line 8 -column 18, line 13 column 18, line 57 -column 19, line 31 column 21, line 26 -column 22, line 4 column 28, line 32 - line 61 ----- WO 94 07225 A (AT COMM INC) 31 March 1994 (1994-03-31) page 5, line 10 -page 10, line 7 -----	1-93
X		1-93

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

<sup>a</sup> Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*&\* document member of the same patent family

Date of the actual completion of the international search

7 November 2001

Date of mailing of the international search report

13/11/2001

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Pham, P

**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

Intern PCT/EP	Application No 01/04972
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